REMARKS

The Office Action mailed on October 2, 2007 was made final. In the Office Action, the Examiner rejected claims 2, 4, and 19 under 35 U.S.C. § 112, first paragraph, as non-compliant with the written description requirement. Claims 2, 5, and 19 were rejected under 35 U.S.C. § 102(b) as being anticipated by WO200023594 ("Gardella"). Claims 2, 4, 5, and 7 were rejected under 35 U.S.C. § 103(a) as being obvious over Gardella in view of U.S. 5,993,817 ("Yoneda").

Claim Amendments

Claims 2 and 5 have been amended to omit SEQ ID NO: 2.

Claim 4 has been amended to recite T helper epitope. Support for this amendment is found, for example, in paragraph [0032] of the specification.

Claims 20 and 22–28 are eligible for rejoinder and have been amended to correct claim dependencies and antecedent basis.

Finality of the Office Action

The Office Action mailed on October 2, 2007 was made final. Applicants respectfully request that the finality of the action be withdrawn.

The Examiner has introduced a new ground of rejection under 35 U.S.C. 102(b) and under 35 U.S.C. 103 (a) over a newly cited reference, Gardella. This new ground of rejection was neither necessitated by Applicants' claim amendments, nor based on information submitted in an information disclosure statement. In the rejection under 35 U.S.C. 102(b), the Examiner stated that "Gardella teach PTHrP peptides and SEQ ID NO:8 on page 26, lines 25–26 that is identical with the instant SEQ NO:2." However, claim 2 as originally filed recited "SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO: 4 and SEQ ID NO: 5 or a functional variant thereof." Therefore, Applicants respectfully submit that the finality of the rejection is improper because it was not necessitated by Applicants' claim amendments, and that the Applicants should be allowed the opportunity to respond to the newly cited reference. Applicants respectfully request reconsideration and withdrawal of the finality of the Office Action.

Rejection of claims 2, 4, and 19 under 35 U.S.C. § 112

Claims 2, 4, and 19 were rejected under 35 U.S.C. § 112, first paragraph, as non-compliant with the written description requirement.

Claim 2 has been amended to remove "or a functional variant thereof." Applicants respectfully submit that in light of this amendment, the rejection of claims 2 and 19 is rendered moot.

The Examiner has maintained the rejection of claim 4 as not satisfying the written description requirement. The Examiner states that "the structure of the 'helper epitope' is not provided and thus the structure of the epitope does not correspond with its function."

Claim 4 has been amended to recite "T helper epitope."

It is well settled that "a description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption." (see MPEP 2163 citation omitted). A person skilled in the art would recognize in Applicants' disclosure a description of the invention including "T helper epitope" as defined by the claims. The Examiner does not address the fact that Applicants' disclosure teaches the use of SEQ ID NO: 6 as a T helper epitope, (see for example, paragraph [0120]). As described in the specification, universal T helper epitopes are well known in the art and in addition to SEQ ID NO. 6 from HBV core antigen, may be derived from tetanus toxoid, pseudomonas aeruginosa toxin A, beta-galactosidase, brucella abortus, keyhole limpet hemocyanin, influenza virus hemagglutinin and nucleoprotein, hepatitis B core and surface antigens, malaria circumsporozoite, and ovalbumin, (see for example, paragraph [0032]). In addition, the specification teaches that T helper motifs such as those described in O'Sullivan et al., *J. Immunol.* 147:2663-2669, 1991, may be used. (see paragraph [0032]).

Therefore, the structure of at least one T helper epitope has been provided in SEQ ID. NO. 6 along with the written description to support claim 4 in compliance with 35 U.S.C. § 112, first paragraph. At the time the application was filed a person skilled in the art would have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the structure of at least one helper epitope along with a description of other suitable helper epitopes in the application as filed. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection of claims 2, 5, and 19 under 35 U.S.C. § 102(b)

Claims 2, 5, and 19 were rejected under 35 U.S.C. § 102(b) as being anticipated by Gardella.

Independent claims 2 and 5 have been amended to remove "SEQ ID NO. :2." Furthermore, independent claim 2 has been amended to remove "or a functional variant thereof."

Gardella discloses SEQ ID NO:8 and selected derivatives thereof. (page 26, lines 25–26). All of the peptides in Gardella require the sequence -Val-Ser-Glu-.

Gardella fails to teach or suggest any of SEQ ID NOs: 3, 4 or 5 as claimed in amended independent claims 2 and 5. Therefore, independent claims 2 and 5 are patentable over Gardella. Claim 19 is dependent on claim 2 and is also patentable over Gardella for at least the above mentioned reason. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection of claims 2, 4, 5, and 7 under 35 U.S.C. § 103(a)

Claims 2, 4, 5, and 7 were rejected under 35 U.S.C. § 103(a) as being obvious over Gardella in view of Yoneda. The Examiner also mentions Bagnoli in the conclusion paragraph of the rejection, stating that "it would be obvious to one of an ordinary skill in the art at the time the invention was made to design a peptide of SEQ ID NOs:2–5 as taught by Bagnoli which comprises a helper epitope as taught by Yoneda because such designs are known in the art and there is a great predictability that such design will work for its intended purposes." However Gardella is not metntioned in the conclusion. Clarification of the rejection over Bagnoli is respectfully requested.

Amended independent claim 2 recites "an isolated immunostimulatory PTH-rP peptide consisting of an amino acid sequence selected from the group consisting of SEQ ID NO:3, SEQ ID NO:4 and SEQ ID NO:5," and amended independent claim 5 recites "an isolated immunostimulatory peptide consisting of two or more amino acid sequences selected from the group consisting of SEQ ID NO:3, SEQ ID NO:4 and SEQ ID NO:5."

Gardella discloses a PTH peptide of generic formula of SEQ. ID NO. 1 and derivatives thereof (page 23, lines 4–19). However, all of the peptides in Gardella require the sequence –

Val-Ser-Glu-. Gardella further proposes that the disclosed peptides can be used in the prevention and treatment of conditions manifested by loss of bone mass such as osteoporosis and osteopenia (see Gardella page 36, lines 3–12). Yoneda teaches the use of PTH and epitopes of PTH to generate anti-PTH antibodies. (Col. 6 lines 1–11). Yoneda discloses only monoclonal antibodies raised against PTH-rP, preferably against the N-terminal region of amino acids 1–34. Bagnoli discloses PTH-rP fragments containing 13–141 amino acids for use in prevention and therapy of abortion and premature birth.

The combination of Gardella in view of Yoneda and Bagnoli do not teach or suggest every element of the claimed invention. Gardella fails to teach or suggest any of SEQ ID NO. 3–5. Moreover, Gardella fails to teach or suggest the use of the disclosed peptides as cancer vaccines or for immunostimulatory purposes. Yoneda and Bagnoli fail to cure this deficiency because neither reference teaches or suggests any of the claimed sequences. There is no teaching or suggestion in Gardella, Yoneda or Bagnoli that any of SEQ ID NOs: 3, 4, or 5 would be useful for any purpose. The teachings of Gardella, Yoneda and Bagnoli either alone or in combination, fail to teach or suggest each and every element of independent claims 2 and 5. Therefore, claims 2 and 5 are patentable over Gardella in view of Bagnoli and Yoneda.

Claim 4 is dependent on claim 2 and claim 7 is dependent on claim 5. Therefore, claims 4 and 7 are also patentable over Gardella in view of Bagnoli and Yoneda. In addition, there is no teaching or suggestion in Gardella, Yoneda, or Bagnoli of an isolated immunostimulatory PTH-rP peptide consisting of an amino acid sequence (or two or more amino acid sequences) selected from the group consisting of SEQ ID NO:3, SEQ ID NO:4, and SEQ ID NO:5 and further comprising a T helper epitope.

Withdrawal and reconsideration of the rejection of claims 2, 4, 5, and 7 are respectfully requested.

CONCLUSION

In view of the foregoing, Applicants respectfully submit that claims 2, 4, 5 ,7, and 19 are in condition for allowance and request favorable action. If the Examiner believes that a telephone conversation with Applicants' attorney would expedite allowance of this application, the Examiner is invited to call the undersigned attorney at (617) 526-9617.

Respectfully submitted,

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